DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m2165n

Food and Drug Administration
Rockville MD 20857

NOV - 6 1998

Federal Express

WARNING LETTER

Sergei Bogojavlensky, M.D.
Fitchburg Professional Building
Suite 1002
47 Ashby State Road
Fitchburg, Massachusetts 01420

Dear Dr. Bogojavlensky:

On September 14, 15 and 17, 1998, Ms.Sandra White, an investigator with the Food and Drug Administation (FDA), New England District Office, conducted an inspection at your facility. The purpose of that inspection was to determine whether your activities and procedures as principal investigator of an investigational study of the [redacted] complied with applicable regulations. This product is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

We have evaluated the inspection report submitted by the District Office, which revealed that there were violations of the requirements of Title 21, Code of Federal Regulations (21CFR), Part 812 - Investigational Device Exemptions (IDE), and Part 50 Protection of Human Subjects. These items were presented to your staff as observations on form FDA-483 and were discussed with [redacted], at the conclusion of the inspection. The following description of violations is not intended to be an all-inclusive list of deficiencies with regard to your clinical study.

1. Failure to conduct the investigation in accordance with the investigational plan and applicable FDA regulations as required by 21 CFR 812.100.

The investigational plan was not followed correctly with regard to the maintenance of study records, in that the following records were not maintained:

[redacted]

FOI purged
on
11-6-98

[redacted]

2. **Failure to keep accurate records of the receipt, use, or disposition of the investigational device as required by 21 CFR 812.140(a)(2).**

No accountability records were maintained documenting the date of receipt and quantity of [redacted]s, the dates and quantity dispensed, and the dates/quantity returned to the sponsor.

3. **Failure to submit timely and accurate reports to the Sponsor or the reviewing IRB as required by 21 CFR 812.150(a).**

Your study was approved in April 1995 by the IRB as a non-signficant risk study. You failed to submit yearly progress reports to the IRB for continuing review consideration, and there was no documentation to show the IRB had approved continuation of the study.

There were no records documenting the submission of a periodic and/or final study summary report to the sponsor, including if IRB approval was ever received.

4. **Failure to obtain IRB approval prior to enrolling patients in the study [21 CFR 812.110(a) and 21 CFR 50.27].**

[redacted] participated in the study on or about February 24, 1995, prior to the IRB approval of the informed consent and protocol.

5. **Failure to provide informed consent in accordance with 21 CFR 50.20.**

There was no documentation that subjects who were enrolled in this study received informed consent.

It is your responsibility to ensure that any future investigational studies will be conducted in accordance with applicable regulations. FDA acknowledges your verbal responses to the field investigator regarding these violations.

Within fifteen working days of receipt of this letter please provide this office with written documentation of any specific steps you have

taken or will be taking to bring any future studies into compliance with FDA regulations.

You should direct your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I, 2098 Gaither Road, Rockville, Maryland 20850, Attention: Alice Rozema. A copy of this letter has been sent to the New England District Office. We request that a copy of your response also be sent to that office at Food and Drug Administration, New England District Office, One Montvale Avenue, 4th floor, Stoneham, Massachusetts 02180.

Please direct all questions concerning this matter to Ms. Rozema at (301) 594-4720, ext. 131.

Sincerely yours,

for Lillian J. Gill
Director
Office of Compliance
Center for Devices
and Radiological Health